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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,278	11/21/2005	Stephan Schwers	71325-015	7785

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EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,278	SCHWERS ET AL.	
	Examiner	Art Unit	
	SARAE BAUSCH	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-104* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 19-20, 85, drawn to SNP that is a C to T SNP.

Group 2, claim(s) 21-22, 86, 98, drawn to SNP that is a A to G to determine adverse drug reaction.

Group 3, claim(s) 23-24, 87, 99 drawn to SNP that is C to G to determine adverse drug reaction.

Group 4, claim(s) 25-26, , 88, 100, drawn to SNP that is A to T to determine adverse drug reaction.

Group 5, claim(s) 27-28, 89, 101, drawn to SNP that is G to T to determine adverse drug reaction.

Group 6, claim(s) 29-30, 90, 102 drawn to SNP that is A to C to determine adverse drug reaction.

Group 7, claim(s) 33, drawn to alleles that are C and T to determine adverse drug reaction.

Group 8, claim(s) 34, drawn to alleles that are A and G to determine adverse drug reaction.

Group 9, claim(s) 35, drawn to alleles that are A and T to determine adverse drug reaction.

Group 10, claim(s) 36, drawn to alleles that are C and G to determine adverse drug reaction.

Group 11, claim(s) 37, drawn to alleles that are A and C to determine adverse drug reaction.

Group 12, claim(s) 38, drawn to alleles that are G and T to determine adverse drug reaction.

Group 13, claim(s) 42-43, 91, drawn to SNP that is a C to T SNP that is an increased risk for high responder.

Group 14, claim(s) 44-45, 92, drawn to SNP that is a C to T SNP that is an increased risk for high responder.

Group 15, claim(s) 46-47, 93, drawn to SNP that is C to G that is an increased risk for high responder.

Group 16, claim(s) 48-49, 94, drawn to SNP that is A to T that is an increased risk for high responder.

Group 17, claim(s) 50-51, 95, drawn to SNP that is G to T that is an increased risk for high responder.

Group 18, claim(s) 52-53, 96, drawn to SNP that is A to C to determine an increased risk for high responder.

Group 19, claim(s) 56, drawn to alleles that are C and T to determine relative risk for high responder.

Group 20, claim(s) 57, drawn to alleles that are A and G to determine relative risk for high responder.

Group 21, claim(s) 58, drawn to alleles that are A and T to determine relative risk for high responder.

Group 22, claim(s) 59, drawn to alleles that are C and G to determine relative risk for high responder.

Group 23, claim(s) 60, drawn to alleles that are A and C to determine relative risk for high responder.

Group 24, claim(s) 61, drawn to alleles that are G and T to determine relative risk for high responder.

Group 25, claim(s) 65-66, 97, drawn to SNP that is a C to T SNP to determine relative risk for CVD.

Group 26, claim(s) 67-68, 98, drawn to SNP that is a C to T SNP to determine relative risk for CVD.

Group 27, claim(s) 69-70, 99, drawn to SNP that is C to G to determine relative risk for CVD.

Group 28, claim(s) 71-72, 100, drawn to SNP that is A to T to determine relative risk for CVD.

Group 29, claim(s) 73-74, 101, drawn to SNP that is G to T determine relative risk for CVD.

Group 30, claim(s) 75-76, 102, drawn to SNP that is A to C to determine relative risk for CVD.

Group 31, claim(s) 79, drawn to alleles that are C and T to determine relative risk for CVD.

Group 32, claim(s) 80, drawn to alleles that are A and G to determine relative risk for CVD.

Group 33, claim(s) 81, drawn to alleles that are A and T to determine relative risk for CVD.

Group 34, claim(s) 82, drawn to alleles that are C and G to determine relative risk for CVD.

Group 35, claim(s) 83, drawn to alleles that are A and C to determine relative risk for CVD.

Group 36, claim(s) 84, drawn to alleles that are G and T to determine relative risk for CVD.

** It is noted the claims 103 and 104 have not been placed in a group as the claims are in an improper multiple dependent form. Upon amendment to the claims, the claims will be placed in an appropriate group and may be subject to further restriction.

2. The inventions listed as Groups 1-36 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be determining the relative risk from statin therapy by genotyping. Pedro-Botet et al. (Atherosclerosis 158 (2001), pp. 183-193) teach determining the affects of atorvastatin on gender by calculating the relative risk of genotype, apoE (see abstract). Pedro-Botet et al. teach analysis of three allele genotypes and teaches calculation of frequency (relative risk) and statistical analysis (see 2.3, pg. 185). Thus, the technical feature linking the recited groups I-12 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

3. Claims 17-18, link(s) inventions of group 1-6. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 17-18.

Claims 31-32, link(s) inventions of group 7-12. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 31-32, 54-55, 77-78.

Claims 40-41, link(s) inventions of group 13-18. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 40-41.

Claims 54-55, link(s) inventions of group 19-24. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 54-55.

Claims 63-64 link(s) inventions of group 25-30. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 63-64.

Claims 77-78 link(s) inventions of group 31-36. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 77-78.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Further Restriction Requirement

4. Additionally, group named above is subject to further restriction. Applicant is required to further elect one primer combination that corresponds specific SNP. For example, if applicant elects group 1, applicant is required to elect primers, such as primers SEQ ID No. 157-160 (baySNP 1722). This is NOT an election of species. Nucleotide sequences s are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Searching more than one of the claimed patentably distinct sequences represents a serious burden to the office.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634